

REMARKS

The present Office Action addresses and rejects claims 1-7 and 28. Applicants respectfully request reconsideration and allowance of the present application in view of the following remarks.

I. Summary of Claimed Subject Matter

Independent claim 1 requires an apparatus for harvesting bone plugs that includes a tube with an inner bore and at least one recess spaced apart from a distal end, and a sheath disposed around the tube and including a distal end having a cutting edge for harvesting a bone plug from bone tissue and a tooth extending towards the inner bore for cutting bone to extract a bone plug.

Independent claim 28 requires an apparatus for harvesting bone plugs that includes a tube with an inner bore and a sheath disposed around the tube. The sheath includes a distal end having a cutting edge for harvesting a bone plug from bone tissue.

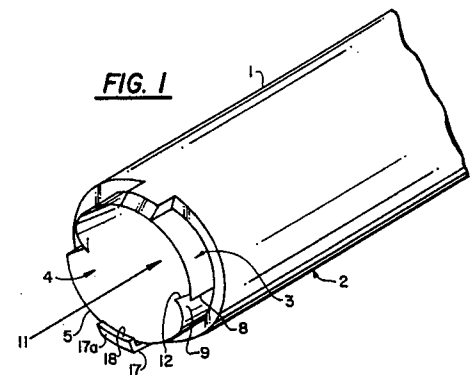
II. The Rejection Of Claims 1-6 and 28 Pursuant To 35 U.S.C. §103(a) Over U.S. Patent No. 5,346,497 of Simon in view of U.S. Patent No. 5,725,495 of Strukel et al. Should Be Reversed

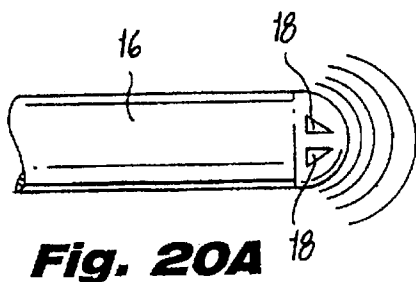
A. The Examiner's Rejection And The Scope And Content Of The Prior Art

The Examiner rejects claims 1-6 and 28 pursuant to 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,346,497 of Simon ("Simon") in view of U.S. Patent No. 5,725,495 of Strukel et al. ("Strukel").

As shown in FIG. 1, reproduced herein, Simon is directed to a cutting head that can be used with other surgical instrument "bodies." The cutting head of Simon includes an inner tube 3 having a cutting surface 5 and an outer guard tube 2.

In the pending rejection, the Examiner argues that the inner cutting tube 2 of Simon is the claimed sheath, but admits that Simon fails to teach or suggest a tube with the sheath and having at least one recess spaced apart from a distal end. The Examiner thus relies on Strukel to teach the claimed tube. In particular, the Examiner argues that at least FIG. 20A of Strukel, reproduced below, illustrates a cutting needle 16 having a recess spaced apart from the end. The Examiner argues that it would have been obvious to a person having ordinary skill in the art to modify the cutting head of Simon to include the cutting





needle of Strukel therein. To provide motivation for such a modification, the Examiner characterizes Simon as teaching that “a remainder of an infusion/aspiration device is applied within the lumen of the sheath.” Since Strukel teaches an infusion/aspiration device, the Examiner argues it would be obvious to modify Simon to include the tube of Strukel to

“allow efficient aspiration of cut tissue and/or irrigation fluid....” *Office Action dated Jan. 13, 2009, page 3.*

B. The Combination Of Simon And Strukel Does Not Render Obvious Claims 1-6 And 28

The Examiner’s rejection should be reversed because (1) the proposed modification is not obvious because there is no advantage or beneficial result expected, (2) the proposed modification is not obvious because it is specifically contrary to the teachings of Simon, and (3) the Examiner’s rejection is improperly based on a mischaracterization of the teachings of Simon.

1. The Proposed Modification Is Not Obvious Because There Is No Advantage or Beneficial Result Expected

There is no advantage or beneficial result to the proposed modification. As noted above, the cutting head of Simon includes an inner tube having a cutting edge for cutting tissue and/or irrigation of fluid. There is absolutely no reason why a person having ordinary skill in the art would modify the device of Simon by inserting an additional cutting element, such as the cutting needle of Strukel, within the lumen, because the device of Simon *already has* a cutting element that both cuts tissue and provides irrigation of tissue. An additional cutting element would be superfluous and useless. The Federal Circuit has held that the strongest rationale for combining references is a recognition that some advantage or expected beneficial result would be produced by the combination. *In re Sernaker*, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir. 1983). Here, there is no advantage to or beneficial result in modifying Simon since the Examiner’s own asserted advantage to the modification is exactly what Simon already achieves with its device, namely efficient aspiration of cut tissue and/or irrigation fluid. No person having ordinary skill in the art would be motivated to make such a modification because the unmodified device of Simon performs the exact same function as the modified device.

2. *The Proposed Modification Is Not Obvious Because It Is Specifically Contrary To the Teachings of Simon*

The modification of Simon as suggested by the Examiner is specifically contrary to the teachings of Simon. The cutting head of Simon is designed with a safety mechanism to give a user greater control over the cutting of tissue by having an outer guard tube that surrounds the inner cutting tube. The inner cutting tube is recessed within the guard tube to prevent the sharp points of the cutting edge from catching tissue, and the outer guard tube has guards that overhang the cutting surfaces of the inner tube to protect against unintended cutting of tissue. In particular, Simon teaches that

the inner tube 3 can be slightly recessed within the exterior tube 2. This...can provide[s] the surgeon with greater control in cutting away only those portions of the lens that need to be removed, and to prevent the sharp points of the cutting edges...from catching and rotating the lens capsule...during surgery. The exterior tube 2 can also be provided, at its proximal end 13, with one or several guards 17...that overhang[s] the proximal end 4 of the inner tube 3...to provide greater control to the surgeon and greater safety to the patient.

Col. 5, line 61 –col. 6, line 17 of Simon (emphasis added).

Modifying the cutting head of Simon to include an additional cutting element, such as the needle of Strukel, that simply extends through the inner tube unprotected and unguarded is specifically contrary to the teachings of Simon. The needle of Strukel would have no guard or protective mechanism associated with it to provide control to the surgeon and safety to the patient, which is taught by Simon as a clear purpose of and advantage to its cutting head. Thus, such a modification would destroy the intended safety and control purpose of the cutting head of Simon. The Federal Circuit has expressly held that a proposed modification of a prior art invention cannot render that invention “unsatisfactory for its intended purpose.” If it does, “there is no suggestion or motivation to make the proposed modification.” *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). The cutting head of Simon modified as the Examiner suggests would no longer offer protection and control over the unintended cutting of tissue and would thus render the device unsatisfactory for its intended purpose.

3. *The Examiner's Rejection Is Improperly Based On A Mischaracterization Of The Teachings Of Simon*

The Examiner's rejection is further improper because it is based on a mischaracterization of the teachings of Simon. More particularly, since Simon does not disclose any portion of a surgical instrument other than the cutting head, Simon notes that certain functions of the cutting head, such as rotation, vibration, etc. of the inner tube, as well as infusion/aspiration through the inner tube, can be accomplished using other "means" *in the remainder* of a surgical instrument body that are not shown. *See Simon, col. 5, lines 33-43.* The Examiner considers the inner tube of Simon as an outer sheath having a lumen that receives the cutting needle of Strukel, and thus the Examiner uses the above noted teaching to argue that Simon teaches that "a remainder of an infusion/aspiration device is applied *within the lumen of the sheath.*" *See Office Action dated Jan. 13, 2009, p. 3* (emphasis added). This is a mischaracterization of the teaching and is in fact contrary to the wording of Simon. The "means" in a "remainder" of a surgical instrument *does not include* "within the lumen of the inner sheath" of Simon, as the Examiner suggests. In particular, Simon distinguishes its cutting head as a separate entity from any other "means" contained within the "remainder" of the surgical instrument. Attempts by the Examiner to characterize this teaching as providing motivation for positioning any "means" *within* the lumen of the inner tube is inappropriate, and thus the Examiner has failed to provide any actual motivation for such a modification.

Accordingly, for all of these reasons, claims 1 and 28, as well as claims 3-6 which depend therefrom, distinguish over Simon in view of Strukel and represent allowable subject matter.

III. The Rejection Of Claim 7 Pursuant To 35 U.S.C. §103(a) Over U.S. Patent No. 5,346,497 of Simon in view of U.S. Patent No. 5,725,495 of Strukel et al. And In Further View of U.S. Patent No. 6,358,253 of Torrie et al. Should Be Reversed

A. *The Examiner's Rejection And The Scope And Content Of The Prior Art*

Claim 7 is rejected pursuant to 35 U.S.C. 103(a) as being obvious over Simon in view of Strukel and in further view of U.S. Patent No. 6,358,253 of Torrie et al. ("Torrie"). The Examiner argues that Simon and Strukel disclose the invention substantially as claimed but fail to teach a bone plug from articular cartilage and underlying bone tissue as required by claim 7. Thus, the Examiner relies on Torrie to teach such a bone plug.

B. The Combination Of Simon, Strukel, and Torrie Does Not Render Obvious Claim 7

As noted in detail above, there is no motivation to combine Simon and Strukel and thus claim 7, which depends from claim 1, distinguishes over the combination of Simon and Strukel for the same reasons as claim 1. Torrie does not remedy the deficiencies of Simon and Strukel, as Torrie likewise fails to teach a tube with an inner bore and a sheath disposed around the tube including a distal end having a cutting edge for harvesting a bone plug from bone tissue. Torrie merely teaches a device for repairing cartilage that can harvest a bone plug. Accordingly, claim 7 distinguishes over Simon in view of Strukel and in further view of Torrie at least because it depends from an allowable base claim.

Conclusion

Applicants submit that all claims are in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

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Respectfully submitted,

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